

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### A comparative study of clinical and radiographic success rates of BMP2 and MTA in pulpotomy of primary molars in 3 to 6 year old children

#### Protocol summary

##### Summary

The purpose of this study is to evaluate clinical and radiographic success and failure rate of MTA and BMP2 in pulpotomy of primary molars in 12 months follow up. This study is a randomized single blind study and is in stage 3 of clinical trial. In this study 3 to 6 year old children with at least two mandibular primary molars need pulpotomy, is studied. A total of 50 teeth are selected. The criteria for selection of teeth are: exposed vital tooth without signs and symptoms and with no clinical or radiographic evidence of pulp degeneration and the possibility of proper restoration of the tooth. Teeth with any sign and symptom and clinical or radiographic evidence of pulp degeneration, physiologic mobility and any pathologic root resorption are excluded from the study. The teeth divided into two equal groups. For all teeth caries are removed and coronal access is completed. After coronal pulp amputation, in one group MTA is used as a pulp dressing agent and in the other group BMP2 is used with gel foam. The teeth are restored with Interim Restorative Material (IRM) and then stainless steel crown is placed. Children are recalled for clinical and radiographic evaluation every 3 months for a total follow up period of one year. The case is regarded as a failure when one or more of the following signs are present: internal and external resorption, radiolucency, widening of periodontal ligament, pain, swelling, sensitive to percussion, pathologic mobility or sinus tract.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017062434726N1**

Registration date: **2017-08-31, 1396/06/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-31, 1396/06/09

##### Registrant information

###### Name

Nosrat Nourbakhsh

###### Name of organization / entity

School of dentistry, Esfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 5591

###### Email address

nourbakhsh@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Dental school, Esfahan University of Medical Sciences; Kowsar Kohangen Company

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of clinical and radiographic success rates of BMP2 and MTA in pulpotomy of primary molars in 3 to 6 year old children

##### Public title

Effect of BMP2 versus MTA as a medicament in pulpotomy of primary molars

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Exposed vital tooth without signs and symptoms; Teeth with no clinical or radiographic evidence of pulp degeneration; The possibility of proper restoration of the tooth. Exclusion criteria: Teeth with signs and symptoms; Clinical or radiographic evidence of pulp degeneration; physiologic mobility; Evidence of any pathological root resorption.

### **Age**

From **3 years** old to **6 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

The Split mouth design is applied in this study. Base on block randomization table all of the participants will be assigned to receive pulpotomy therapy with MTA in primary mandibular molars of one side and pulpotomy with BMP2 in primary mandibular molars of another side.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

##### **Street address**

Ethics committee, Dental school, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan

##### **City**

Esfahan

##### **Postal code**

#### **Approval date**

2016-05-27, 1395/03/07

#### **Ethics committee reference number**

IR.MUI.REC.1395.3.753

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

reversible pulpitis

#### **ICD-10 code**

k04.0

#### **ICD-10 code description**

reversible pulpitis

## **Primary outcomes**

### **1**

#### **Description**

pain

#### **Timepoint**

before intervention, 3 months, 6months, 9months and 12 months after intervention

#### **Method of measurement**

clinical examination

### **2**

#### **Description**

sensitive to percussion

#### **Timepoint**

before intervention, 3 months, 6months, 9months and 12 months after intervention

#### **Method of measurement**

clinical examination

### **3**

#### **Description**

swelling

#### **Timepoint**

before intervention, 3 months, 6months, 9months and 12 months after intervention

#### **Method of measurement**

clinical examination

### **4**

#### **Description**

sinus tract

#### **Timepoint**

before intervention, 3 months, 6months, 9months and 12 months after intervention

#### **Method of measurement**

clinical examination

### **5**

#### **Description**

pathologic mobility

#### **Timepoint**

before intervention, 3 months, 6months, 9months and 12 months after intervention

#### **Method of measurement**

clinical examination

## Secondary outcomes

### 1

#### Description

internal resorption

#### Timepoint

before intervention, 3months, 6months, 9months and 12months after intervention

#### Method of measurement

radiographic examination

### 2

#### Description

external resorption

#### Timepoint

before intervention, 3months, 6months, 9months and 12months after intervention

#### Method of measurement

radiographic examination

### 3

#### Description

PDL widening

#### Timepoint

before intervention, 3months, 6months, 9months and 12months after intervention

#### Method of measurement

radiographic examination

### 4

#### Description

radiolucency

#### Timepoint

before intervention, 3months, 6months, 9months and 12months after intervention

#### Method of measurement

radiographic examination

## Intervention groups

### 1

#### Description

Intervention group: After pulpotomy treatment, 1 microgram recombinant human bone morphogenetic protein 2 (rhBMP2) is placed in pulp chamber.

#### Category

Treatment - Other

### 2

#### Description

group2: After pulpotomy treatment, MTA paste is placed in pulp chamber as a standard pulpotomy medicament.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Pediatric Department, School of Dentistry, Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Nosrat Nourbakhsh

##### Street address

School of Dentistry, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan

##### City

Esfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Esfahan University of Medical Sciences

##### Full name of responsible person

Elham Sadat Binande

##### Street address

Vice chancellor for research, Dental school, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan

##### City

Esfahan

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Esfahan University of Medical Sciences

#### Proportion provided by this source

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

### 2

#### Sponsor

##### Name of organization / entity

Kowsar Kohan Gen company

##### Full name of responsible person

Amir Hossein Behnia

##### Street address

Flat. A13, Ghadir street

**City**  
Sepahanshahr

**Grant name**  
-

**Grant code / Reference number**  
-

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Kowsar Kohan Gen company

**Proportion provided by this source**

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences

**Full name of responsible person**  
Dr Sanaz Ziaei

**Position**  
Resident of pediatric dentistry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Position**  
Resident of pediatric dentistry

**Other areas of specialty/work**

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**Postal code**

**Phone**  
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**Email**  
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sanaz20\_2005@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*